SOMANETICS®

K091224 510(k) Summary

Date of Submission: ..... June 12, 2009

Device Trade Name: ..... Modifications to OxyAlert NIRSensors, model IS-C and IS-S

Device Common Name: ..... Accessory for Oximeter, Cerebral/Somatic

Device Classification Name: ..... Oximeter, Tissue Saturation (21 CFR 870.2700, Product Code MUD)

Submitted by: ..... Somanetics Corporation
1653 East Maple Road
Troy, MI 48083
Phone: 248-689-3050
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Contact Person: ..... Ronald A. Widman
Vice President, Medical Affairs
248-526-5865
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Predicate Device: ..... Somanetics INVOS 5100C Cerebral/Somatic Oximeter System, K082327

Accessories .....

SAFB-SM	Small Adult SomaSensor (>40 kg)
SPFB	Pediatric SomaSensor (<40 kg)
IS-C	Infant/Neonatal Cerebral OxyAlert NIRSensor (<40 kg)
IS-S	Infant/Neonatal Somatic OxyAlert NIRSensor (<40 kg)
RSC-1	Reusable Sensor Cable Channel 1
RSC-2	Reusable Sensor Cable Channel 2
RSC-3	Reusable Sensor Cable Channel 3
RSC-4	Reusable Sensor Cable Channel 4
5100C-W	One-year Extension of Warranty
5100C-M	5100C System Operations Manual
5100-FTD	Field Test Device
5100C-RS	Portable Mobile Stand
5100C-SA	Swivel Arm
5100C-GCX	Mounting Plate
5100C-TC	Travel Case
5100C-USB	USB Flash Drive
312170	Computer Connection Serial Cable
VL1	Philips VueLink Adaptor Cable

Indications for Use:	The noninvasive INVOS 5100C is intended for use as an adjunct monitor of regional hemoglobin oxygen saturation of blood in the brain or in other tissue beneath the sensor. It is intended for use in individuals greater than 2.5 kg at risk for reduced-flow or no-flow ischemic states. It is also intended for use as an adjunct trend monitor of regional hemoglobin oxygen saturation of blood in the brain or in other tissue beneath the sensor in any individual.
Predicate Device	INVOS® 5100C Cerebral/Somatic Oximeter System
Technological Characteristics:	The INVOS 5100C is a 2 wavelength, diffuse reflectance spectroscopy system employing near infrared light to estimate the percentage of hemoglobin saturated with oxygen in tissue underneath the sensor. An adhesive sensor containing a light source and 2 photodiodes is applied to the skin over the tissue of interest and the returning light is analyzed for oxyhemoglobin and deoxyhemoglobin light absorption. Absorption signals from the photodiode closer to the light source are subtracted from those from the farther photodiode where the returning photons penetrate more deeply in the tissue. This suppresses absorption events originating in the outer layers of tissue that are common to both photodiodes, including the effects of skin pigmentation and subcutaneous tissues. This method of "spatial resolution" also allows estimation of scattering to improve measurement accuracy.
Performance Data:	Bench testing is submitted demonstrating the substantial equivalence of the new sensors with modified photodiodes for the stated indication.
Substantial Equivalence:	The new sensors have the same intended use and indications, principles of operation and technological characteristics as the predicate device. The change in photodiodes does not raise any new questions of safety or effectiveness. Performance data demonstrates that the new photodiodes are as safe and effective as the predicate. Thus, the

modified sensors are substantially equivalent to the predicate sensors.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 9 2009

Somanetics Corporation
c/o Ronald A. Widman
1653 East Maple Rd.,
Troy, MI 48083-4208

Re: K091224
Trade/Device Name: OxyAlert NIRSensor Models IS-C and IS-S
Accessories for Somanetics INVOS 5100C System
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: MUD
Dated: June 12, 2009
Received: June 16, 2009

Dear Mr. Widman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number K091224

Device Name: Somanetics INVOS® 5100C System and Accessories

Indications For Use:

The noninvasive INVOS 5100C is intended for use as an adjunct monitor of regional hemoglobin oxygen saturation of blood in the brain or in other tissue beneath the sensor. It is intended for use in individuals greater than 2.5 kg at risk for reduced-flow or no-flow ischemic states. It is also intended for use as an adjunct trend monitor of regional hemoglobin oxygen saturation of blood in the brain or in other tissue beneath the sensor in any individual.

Prescription Use__X___ (Part 21 CFR 801 subpart D) OR Over-The-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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